

AMENDMENTS TO THE CLAIMS

1- 34. (Cancelled).

35 (Newly Presented). A non-hygroscopic, glassy lozenge useful for transmucosal, oral administration of a nicotine active, comprising a glassy matrix base comprising isomalt; from about 0.5 mg to about 5mg of a nicotine active; and one or more water soluble gelling gums in an amount sufficient to provide an oral dissolution rate of said glassy matrix such that at least 80% of the nicotine active is absorbed via the oral mucosa; wherein the lozenge is prepared by a process comprising the steps of

- a) mixing and heating isomalt with a diluent to form a melt;
- b) cooking said melt;
- c) removing excess moisture from the melt;
- d) cooling the melt with mixing until the melt is a workable mass;
- e) incorporating the nicotine and one or more water soluble gelling gums into the workable mass to form a mixture; and
- f) forming the mixture into lozenges

36 (Newly Presented). The lozenge prepared by the process of claim 35, wherein a further active agent selected from the group consisting of cold agents, cough agents, throat agents, vitamins, zinc, menthol, eucalyptus, hexylresorcinol, caffeine, tooth whitening agents, anti-plaque agents and breath freshening agents is incorporated into workable mass of step e).

37. (Newly Presented). The lozenge prepared by the process of claim 35 wherein said one or more water soluble gelling gums are selected from the group consisting of xanthan gum, guar gum, gum arabic, alginates and carageenan.

38. (Newly Presented). The lozenge prepared by the process of claim 35 wherein said one or more water soluble gelling gum is xanthan gum.

39. (Newly Presented). The lozenge prepared by the process of claim 35 wherein said one or more water soluble gelling gum is present in an amount sufficient to provide that said dosage form dissolves orally over a period of about 10 to 15 minutes.

40. (Newly Presented). The lozenge prepared by the process of claim 35 wherein said one or more water soluble gelling gum is present in an amount of from about 0.5 to about 5.0 percent by weight of the lozenge.

41. (Newly Presented). The lozenge prepared by the process of claim 40 wherein said one or more water soluble gelling gum is present in an amount of from about 1.0 to about 4.0 percent by weight of the lozenge.

42. (Newly Presented). The lozenge prepared by the process of claim 41 wherein said one or more water soluble gelling gum is present in an amount of from about 1.0 to 3.5 percent by weight of the lozenge

43. (Newly Presented). The lozenge prepared by the process of claim 35 comprising at least about 50% of isomalt, based on weight of the lozenge.

44. (Newly Presented). The lozenge prepared by the process of claim 35 comprising at least about 70% of isomalt, based on weight of the lozenge.

45. (Newly Presented). The lozenge prepared by the process of claim 35 comprising at least about 85% of isomalt, based on weight of the lozenge.

46. (Newly Presented). The lozenge prepared by the process of claim 35 wherein the nicotine active is selected from nicotine oil, nicotine bitartrate, nicotine polacrilex and combinations thereof.

47. (Newly Presented). The lozenge prepared by the process of claim 35 further comprising incorporating a buffer in an amount effective to provide an alkaline mouth saliva pH into the workable mass of step e).

48. (Newly Presented). The lozenge prepared by the process of claim 47 wherein the buffer is selected from sodium carbonate, sodium bicarbonate, calcium carbonate, potassium carbonate, potassium bicarbonate, sodium phosphate dibasic, sodium phosphate tribasic, potassium phosphate dibasic, potassium phosphate tribasic, and combinations thereof.

49. (Newly Presented). The lozenge prepared by the process of claim 48 wherein the buffer is selected from sodium carbonate, potassium carbonate, and combinations thereof.

50. (Newly Presented). The lozenge prepared by the process of claim 35 wherein step a) further comprises mixing and heating one or more compounds selected from the group consisting of sucrose, sorbitol, and xylitol with the isomalt and diluent to form a melt.

51. (Newly Presented). The lozenge prepared by the process of claim 35 further comprising incorporating a non-pharmacological component for providing a sensory signal effective to provide rapid nicotine craving relief into the workable mass of step e).

52. (Newly Presented). A method of reducing nicotine cravings comprising orally administering a lozenge prepared by the process of claim 35 to a person in need of nicotine craving reduction.

53. (Newly Presented). A method of reducing tobacco usage comprising orally administering a lozenge prepared by the process of claim 35 to a person in need of reducing tobacco usage.